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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,396	11/09/2001	John Tallman	99,130-I	6851

7590

05/04/2005

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EXAMINER

BRANNOCK, MICHAEL T

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 05/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/045,396

Applicant(s)

TALLMAN ET AL.

Examiner

Michael Brannock

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on none is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>013103</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application: Claims and Amendments

Applicant's election (2/3/05) of claims 1-8 and 10 is acknowledged. Claims 9 and 12-50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. As no arguments were presented as to why the restriction requirement might be improper, the election is treated as being made **without** traverse; thus the restriction requirement is maintained and made FINAL.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence(s) of the specification or in an application data sheet by identifying the prior application by application number (37 CFR 1.78(a)(2) and (a)(5)). If the prior application is a non-provisional application, the specific reference must also include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dawson-G, U.S. Patent No: 6426343 which has an effective US filing date of February 24, 1997.

The invention of the instant claims is predicated on the idea that selective inverse agonism of GABA alpha 5 receptors, while minimizing activity of receptors having alpha 2 and 3 receptor subtypes, will produce cognitive enhancing effects while minimizing pro-convulsive effects, see page 9.

Dawson teaches this principle, see the Abstract, and also teach an assay that measures the in vitro efficacy of a compound and affinity of the compound on $\alpha 5\beta 3\gamma 2$ receptors and comparing these parameters of the compound toward receptors having the $\alpha 2$ and $\alpha 3$ subtypes, and choosing the compound that has an is an inverse agonist of the $\alpha 5\beta 3\gamma 2$ (i.e. has a negative in vitro efficacy value) and has little or no activity at the other receptors, see col 6 and column 8, line 65 through column 10. Dawson does not measure the EC50 value of the compounds, rather Dawson uses the binding affinity of the compound toward the receptors to screen for compound specific to the $\alpha 5\beta 3\gamma 2$ receptors, see col 2, line 62 through col 3, line 14. Regardless, these parameters are all well known and established in the art. One of ordinary skill in the art of pharmacology would not need to be taught a particular number or parameter to use as this would

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readily be apparent during routine optimization of operating parameters. Further, claim 10 requires the additional steps of evaluating the compounds for pro-convulsive and cognitive enhancing effects. These steps are taught by Dawson beginning at col 7.

Claims 1-8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dawson-G, WO96/25948, published 29 August 1996.

The invention of the instant claims is predicated on the idea that selective inverse agonism of GABA alpha 5 receptors, while minimizing activity of receptors having alpha 2 and 3 receptor subtypes, will produce cognitive enhancing effects while minimizing pro-convulsive effects, see page 9.

Dawson teaches this principle, see pages 1-3, and also teach an assay that measures the in vitro efficacy of a compound and affinity of the compound on $\alpha 5\beta 3\gamma 2$ receptors and comparing these parameters of the compound toward receptors having the $\alpha 2$ and $\alpha 3$ subtypes, and choosing the compound that has an is an inverse agonist of the $\alpha 5\beta 3\gamma 2$ (i.e. has a negative in vitro efficacy value) and has little or no activity at the other receptors, see pages 11-13. Dawson does not measure the EC50 value of the compounds, rather Dawson uses the binding affinity of the compound toward the receptors to screen for compound specific to the $\alpha 5\beta 3\gamma 2$ receptors, see page 3. Regardless, these parameters are all well known and established in the art. One of ordinary skill in the art of pharmacology would not need to be taught a particular number or parameter to use as this would readily be apparent during routine optimization of operating parameters. Further, claim 10 requires the additional steps of evaluating the compounds for pro-convulsive and cognitive enhancing effects. These steps are taught by Dawson at pages 13-16.

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Conclusion

Please note the new central fax number for official correspondence below:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (571) 272-0869. The examiner can normally be reached on Mondays through Fridays from 10:00 a.m. to 4:00 p.m.

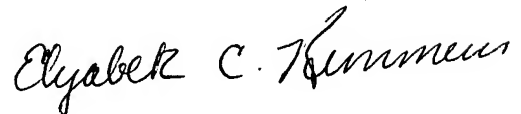
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D., can be reached at (571) 272-0829. Official papers filed by fax should be directed to 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MB



April 29, 2005



**ELIZABETH KEMMERER
PRIMARY EXAMINER**